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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,371	05/16/2001	Alison Davies	DAV 13002REF	9780
7590 03/02/2004			EXAMINER	
Bacon & Thomas 625 Slaters Lane Fourth Floor Alexandria, VA 22314-1176			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,371

Applicant(s)

DAVIES, ALISON

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003 and 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 4-9 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 2, 4-9, 11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2, 4-9, 11-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

1. Applicant's election without traverse of Group I, Claims 2, 4-9, and 11-16, filed 7/10/03, is acknowledged. Applicant's election without traverse of the species: cancer therapy, filed 12/09/03, is acknowledged.

2. Claim 12 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 2, 4-9, 11, and 13-16 are being acted upon.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 4-9, 11, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/33891 (IDS) in view of WO 89/04168 (IDS).

WO 98/33891 teaches a method of autologous therapeutic transplantation therapy of a malignancy (cancer) of a host organism, said method comprising transplanting a host organism with a cell composition prepared from a host cell population of mature T lymphocyte cells obtained from blood of said host organism. The reference further teaches the reconstitution of an immune system damaged by disease (see particularly page 17) and the use of a genetically modified cell (see particularly page 17). The reference also teaches that cells may be cryogenically stored for later use (see particularly page 9) and may be obtained from an adult human (see particularly Example 6).

The reference teaching differs from the claimed invention only in that it does not teach the preparation of the lymphocytes from the host organism before the development of disease (uncompromised).

WO 89/04168 teaches the preservation of neonatal hematopoietic cells for later use in the treatment or prevention of disease (see particularly SUMMARY OF THE INVENTION).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of autologous therapeutic transplantation therapy of a malignancy (cancer) of a host organism, said method comprising preparing and storing lymphocytes from the host organism before the development of disease (uncompromised) and transplanting a host organism with a cell composition prepared from a host cell population of mature lymphocyte cells obtained from blood of said host organism damaged by disease including the use of a genetically modified cell or a cell obtained from an adult human, as taught by WO 98/33891, given the teachings of WO 89/04168. One of ordinary skill in the art at the time the invention was made would have been motivated to prepare and store adult lymphocytes because neonatal lymphocytes (including umbilical cord cells) are available only for a very short time period (at birth) whereas adult cells might be obtained and stored anytime before the development of a disease for which they might become a valuable therapeutic tool.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 4-9, 11, and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically, Claim 2 is ungrammatical in the repetition of the phrase "said method comprising transplanting therapy of a disease or disorder of a host organism".

7. No claim is allowed.

8 Applicant appears to have submitted 6 separate IDS's (Form 1449's). It appears that the IDS's submitted 7/10/03 are duplicates of the IDS's submitted 8/17/01 and 2/01/02. None of the references from said submissions, nor the references on the IDS submitted 5/16/01, have been received by the Examiner. Also, the Newiss reference on the IDS submitted 8/17/01 has not been received by the Examiner.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail


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service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.

G.R. Ewoldt, Ph.D.
Primary Examiner
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2/25/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER